REMARKS

Claims 16-20 and 22-24 are pending. Claim 20 is independent. The amendment to Claim 20 is editorial in nature and support can be found in previous Claim 20. No new matter is incorporated by the Amendment.

Rejection under 35 U.S.C. § 112, Second Paragraph

The rejection of Claim 20 under 35 U.S.C. § 112, second paragraph is addressed by the claim amendment. Reconsideration and withdrawal is respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 16-20 and 22-24 are rejected under 35 U.S.C. § 103(a) as being unpatenable based on Cooper, U.S. Patent No. 5,051,408 alone.

Applicants claims are directed to a method for the inhibition or treatment of systemic infections in humans or vertebrates comprising administering to humans or vertebrates having a systemic infection caused by pathogenic bacteria a composition comprising an effective amount of a fermentable dietary fiber or a mixture of fermentable dietary fibers, wherein the composition is administered orally or through tube feeding.

Cooper fails to teach or suggest the claimed invention.

In reliance on the disclosure of Cooper, the Office Action cites col.12, ll.4-11, reproduced as follows:

> "Infections with microbes, worms or parasites, particularly those of a more chronic course, are likely to be combatted by appropriate treatment with gamma inulin, with or without other immune modulators. Other immune disorders such as allergic or rheumatic diseases, immune deficiency diseases, or neurological or gastro-intestinal disorders related to dysfunction of the immune system, ar likely to be similarly responsive."

Contrary to the characterization given in the Office Action, Cooper teaches methods involving "gamma inulin" which is a particular crystalline form of inulin. In addition, the methods in Cooper are not methods involving systemic infection, but methods directed to the prevention of cancer through activation of the alternate pathway of complement (APC) by injecting gamma inulin into a subject by i.p. injection. See Example 2, col.7, l.58 to col.9, l.11.

Gamma inulin introduced by i.p. injection is not a fermentable dietary fiber that can be fermented by micro-organisms in the large intestine to produce short-chain carboxylic acids (e.g., acetate, propionate or butyrate). Gamma inulin is characterized as having a molecular weight in the range of from about 8,000 to about 16,000 (corresponding to an approximate DP range of 50 to about 100) and is "virtually insoluble" in water. See col.2, ll.17-19. In contrast to the composition of the present invention in which, after oral administration, the dietary fiber is fermented by micro-organisms in the large intestine to produce short-chain carboxylic acids (e.g. acetate, propionate or butyrate), gamma inulin introduced by i.p. injection according to Cooper is not fermented at all. In contrast, the fermentable fibers according to the invention have a substantially lower average polymerization. The criticality of the degree of polymerization is clearly demonstrated in the data presented in Fig. 1 and Fig. 2 of the specification, taking into account the average DP of about 25 for RAFTILINE®HP and of about 3.5 to 4.5 for RAFTILOSE®P95.

Applicants note that Cooper, fails to teach or suggest a method of treating or inhibiting systemic infections by a route that involves administration orally or by tube feeding. The only method supported by the disclosure and examples in Cooper is i.p. injection. The difference follows that the physiologically active agents in the present

invention are entirely different from the physiologically active agents in Cooper due to the method of administration. In the i.p. administration of Cooper, the gamma-inulin is not fermented and is not resorbed; thus the agent is the gamma-inulin itself. In the oral administration of the present invention, the fibers are fermented in the large intestine, and thus the active agents are the short-chain carboxylic acid fermentation products that are then absorbed following the fermentation.

The disclosure of Cooper is directed to a particular crystalline form of inulin. In particular, Cooper is directed to the provision of a preparation which, when administered (by i.p.; s.c.; i.v.; or intra-tumor [col.4, ll.57-60]) to a patient suffering from cancer, will affect the APC to reproducibly and significantly increase the survival time or improve the quality of life of that patient (col.3, l.65 to col 4, l.2). Furthermore, the claimed method involves a biological process, the unpredictability of which is established in the results illustrated in Figures 1 and 2 in the specification.

Finally, the cited disclosure from Cooper at col.12, ll.4-11, relates to treating pathogens that are external in nature, vis-à-vis the body of the affected host. There is no teaching or suggestion that the pathogens involve a systemic infection. The methodology disclosed in Cooper at col.9, ll.30-47 and col.12, ll.4-11, is conjectural and, in itself, would not be enabling of a method for the inhibition or treatment of systemic infections in humans or vertebrates comprising administering to humans or vertebrates having a systemic infection caused by pathogenic bacteria a composition comprising an effective amount of a fermentable dietary fiber or a mixture of fermentable dietary fibers, wherein the composition is administered orally or through tube feeding. Cooper has not supported by experimental data any effect of gamma inulin (either administered by i.p. or administered orally) against

systemic infections by pathogenic bacteria, and as such is merely speculative.

For all the above reasons, reconsideration an withdrawal of the obviousness rejection is respectfully requested.

CONCLUSION

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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MARKED-UP COPY OF AMENDED CLAIMS

20. (Amended) A method for the inhibition [and/or] or treatment of systemic infections in humans or vertebrates comprising administering to humans or vertebrates having a systemic infection caused by pathogenic bacteria a composition comprising an effective amount of a fermentable dietary fiber or a mixture of fermentable dietary fibers, wherein the composition is administered orally [,] or through tube feeding [or rectally].